

## **REMARKS**

In the Office Action dated September 20, 2004, claims 27 -52 are pending, claims 27-45, 47 and 48 are being examined, and claims 46 and 49-52 are withdrawn from consideration. Claims 27-45, 47 and 48 are rejected. Reconsideration is requested at least for the reasons discussed hereinbelow.

Applicants intend to focus the present claims on the cosmetic subject matter and pursue the therapeutic subject matter in a divisional application. As such it is requested that claims 46 and 49-52 be examined together with the present claims, as amended. Amended new claim 26 is now directed to a cosmetic treatment, which is a major aspect of the present invention (see claims 12 and 21 of the PCT application as filed; p. 7, last paragraph; p. 7, 1. 30-31; p. 23, central para.,; p. 27, 1. 22-24). Method claims 46-48 and composition claims 49-52 also follow a cosmetic concept and therefore should be maintained in the present application.

Claims 27-31, 24 [sic, 34] and 38 are rejected under the judicially created doctrine of double patenting over claims 2-7 of U.S. 6,071,526. Applicants strongly disagree.

Applicants submit that the scope of present claim 27 is distinct from the method claimed in the applicant's earlier U.S. Patent No. 6,071,526. The '526 patent claims a method of treating cellulite in such a way that the subcutaneous connective fatty tissue disturbances are improved. As is made very clear in the present application (see page 23, last paragraph [note that US '526 corresponds to earlier PCT

application WO-A-97/36570 cited in this text passage]), the treatment of cellulite addressed in US '526 is directed to fatty connective tissue of the subcutis (inner skin), whereas the presently claimed cosmetic treatment involves the stabilization, the increase or the restoration of collagen. In other words, the presently claimed invention is directed to the part of the skin which particularly contains collagen, especially the cutis as well as other parts of the body which strongly contains collagen. Thus, purpose, cause and reason for treatment and the effects associated with the treatment are different in each case, and these differences are reflected in the "method of treatment" claims, respectively.

Thus it is not seen how the present claims would have been obvious to one of ordinary skill in the art from claims 2-7 of US 6,071,526.

Claims 27-45, 47 and 48 are rejected under 35 U.S.C. §112, second paragraph. It is believed that the amendments overcome this rejection. As suggested by the Examiner, the phrase "to said mammal" has been introduced into claim 27, the word "use" has been deleted in claim 34, and claim 36 has been amended as suggested by the Examiner. In claim 38, the body region is clarified, namely to that which is cosmetically treated. Claim 39 is clarified. In claim 47, the objected expression "upper skin" is replaced by "outer skin" (see bottom of page 22). By the expression "outer skin," Applicants particularly referring to the corresponding anatomic site "cutis (epidermis and corium)" (see p. 23, 1. 26-31).

New claim 53 specifically recites the preferred local, topical application (see p. 17, 1. 30-31).

Claims 27-40 are rejected under 35 U.S.C. §102(e) over Schmidt et al. (US 5,945,109). Applicants respectfully disagree. Schmidt also corresponds WO-A-97/36570 and is similar to US 6,071,526 discussed above. Thus, as already explained in the present application (last paragraph on p. 23 to the bottom of page 24), Schmidt is directed only to subcutaneous connective fatty tissue. Further, there is not even a hint of a suggestion in Schmidt for a stabilization, increase or restoration of collagen.

The Examiner refers to MPEP 2112.02 and related case law (PROCESS CLAIMS-PRIOR ART DEVICE ANTICIPATES A CLAIMED PROCESS IF THE DEVICE CARRIES OUT THE PROCESS DURING). Applicants respectfully disagree that such law applies here.

First, the teaching of Schmidt does not relate to a device and the presently claimed invention, as set forth in claim 27, relates to a specific method of treatment. One skilled in the art would not treat a patient for the indications of the present invention based on the teachings of Schmidt. Thus, it is respectfully submitted that MPEP cited by the Examiner is not relevant here. Further, even assuming that a skilled person might apply a substance according to Schmidt et al. with the intention to cosmetically treat subcutaneous connective fatty tissue disturbances, he would not necessarily (or inherently) perform the method as instantly claimed. Rather, distinctive differences still exist. for example, the present treatment is for a different purpose, a different cause and/or a different reason for treatment, and a different result is obtained thereby. Consequently, a different application mode and time can

apply to achieve the desired results. Also, a different effective amount can apply. It is submitted that these differences should be acknowledged here in view of the presently claimed invention being directed to cosmetic treatment methods. Thus, the treatment of Schmidt would not inherently provide the benefits of the present invention.

Claims 27, 28 and 45 are rejected under 35 U.S.C. §102(b) over Fritz et al. (Endocrine (1998), 139(8): 3399). fritz fails to teach or suggest a method for for a stabilization, increase or restoration of collagen. Applicants respectfully submit that Fritz is remote from the presently claimed subject-matter. More specifically, the therapeutic concept of Fritz et al. is basically different from the cosmetic concepts of the instant claims. Furthermore, the Examiner's remarks on "inherency" also do not apply here, as already explained above in connection with Schmidt. Claim 45 has been cancelled for the present application. Thus, references to that subject matter are moot at this time.

Claims 27, 28 39, 41 and 43 are rejected under 35 U.S.C. §102(e) over Grainger (US 5,770,609). Grainger is directed to therapeutic applications of Tamoxifen. There is no teaching or suggestion in Grainger for a stabilization, increase or restoration of collagen.

Claims 27, 28, 39 and 42 are rejected under 35 U.S.C. §102(b) over Nikura et al (US 5,254,594). Nikura teaches another therapeutic application of Tamoxifen. Again, there is no teaching or suggestion for a stabilization, increase or restoration of collagen.

Claims 27, 28, 39 and 42 are rejected under 35 U.S.C. §102(b) over Sannti et al (US 5,972,921). Sannti teaches another therapeutic application of an aromatase inhibitor relating to treatment of detrusor urethral sphincter dyssynergia in men. Again, there is no teaching or suggestion for a stabilization, increase or restoration of collagen.

Claims 27, 28, 37-40, 47 and 48 are rejected under 35 U.S.C. §102(e) over Tanabe et al (US 6,455,517). Tanabe relates to estrogen-dependent disorders including skin and vagina atrophy in post-menopausal women. Thus, Tanabe teaches therapeutic applications. This seems to be confirmed by the fact that patients, who were suffering from UV-caused damage from the sun leading to dermal atrophy, were excluded from the method of treatments of Tanabe et al. (see col. 83, 1. 42-45). Thus, there is no teaching or suggestion whatsoever in Tanabe for a method for a stabilization, increase or restoration of collagen.

Claims 27, 28, 37-40, 47 and 48 are rejected also under 35 U.S.C. §103(a) over Tanabe. Applicants respectfully disagree. The examiner admits that Tanabe fails to disclose administration of Tamoxifen for treatment of facial wrinkles or ameliorating the effects of the sun on the skin. As aforesaid, Tanabe has not even a hint of a suggestion for a method for a stabilization, increase or restoration of collagen, as presently claimed.

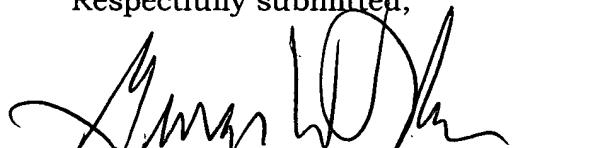
The examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Tamoxifen for this purpose because it is an anti-estrogen and will inherently cause a restoration or increase in collagen in

a mammal. This conclusion is wholly unsupported by any facts of record. Nowhere in the cited art is it taught that an anti-estrogen will inherently cause a restoration or increase in collagen in a mammal. This is the discovery of Applicants. Tanabe et al. as discussed above merely teaches that novel anti-estrogenic compounds having a 1,3,5-estratrien nucleous can be used to replace conventional Tamoxifen chemotherapy.

In view of the above discussion, it is respectfully submitted that the present application is in condition for allowance. An early reconsideration and notice of allowance are earnestly solicited.

If for any reason an additional fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge or to refund Deposit Account No. **04-1105**.

Respectfully submitted,

  
George W. Neuner  
Reg. No. 26,964

Date: January 20, 2005

EDWARDS & ANGELL, LLP  
P.O. Box 55874  
Boston, MA 02205

Tel: (617) 439-4444

Customer No.: 21,874